REGISTRATION REPORT
Part A
Risk Management

Product code: Prothioconazole 300 EC
Product name: TARTAROS
Chemical active substance:
prothioconazole, 300 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(New application)

Applicant: HELM AG
Date: April 2021

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PART A

RISK MANAGEMENT

1 Details of the application

The company HELM AG has requested a marketing authorisation in France for the product TARTAROS (product code: PROTHIOCONAZOLE 300 EC), containing 300 g/L prothioconazole[1], as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report (RR) concerns the evaluation of HELM AG's application submitted on 31/05/2018 to market TARTAROS (PROTHIOCONAZOLE 300 EC) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-1270) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of TARTAROS (PROTHIOCONAZOLE 300 EC) has been made using endpoints agreed in the EU peer review of prothioconazole. It also includes assessment of data and information related to TARTAROS (PROTHIOCONAZOLE 300 EC) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of TARTAROS (PROTHIOCONAZOLE 300 EC).

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1 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: "*The application is for approval of authorization for a new product. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013*".

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TARTAROS (PROTHIOCONAZOLE 300 EC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	Prothioconazole 300 EC.
Product name in MS	TARTAROS.
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Fungicide.
Applicant	HELM AG
Active substance(s) (incl. content)	Prothioconazole, 300 g/L.
Formulation type	Emulsifiable concentrate [EC].
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	None.
Restrictions related to identity	None.
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for TARTAROS (PROTHIOCONAZOLE 300 EC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (oral), category 4. Skin irritation, category 2. Serious eye damage, category 1. Hazardous to the aquatic environment - chronic hazard, category 1.
Hazard pictograms:	 GHS05 GHS07 GHS09
Signal word:	Danger.
Hazard statement(s):	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[5] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;

[5] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, *amended by the* arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

The applicant is required to comply with the current applicable standard for PPEs, more specifically standard ISO EN 27065[8] for clothing type PPE.

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9
[8] Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: April 2021

PPP (product name/code):	Prothioconazole 300 EC	Formulation type:	Emulsifiable concentrate (EC) [a, b]
Active substance 1:	Prothioconazole	Conc. of a.s. 1:	300 g/L [c]
Applicant:	HELM AG	Professional use:	☒
Zone(s):	Southern zone [d]	Non-professional use:	☐
Verified by MS:	yes		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application** Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	**Application rate** L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter / *Triticum durum* winter	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

2	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter/ *Triticum durum* winter	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
3	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter/ *Triticum durum* winter	F	LEPTNO Glume blotch of wheat *Parastagonospora nodor*um	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
4	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter/ *Triticum durum* winter	F	FUSASP Fusarium ear blight of cereals *Fusarium* sp	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)
5	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter/ *Triticum durum* winter	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

6	FR	TRZAW/TRZDW Winter wheat *Triticum aestivum* winter/ *Triticum durum* winter	F	PYRNTR Yellow leaf blotch of wheat *Pyrenophora tritici-repentis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
7	FR	HORVW Winter barley *Hordeum vulgare* winter	F	PUCCCHD Dwarf leaf rust of barley *Puccinia hordei*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
8	FR	HORVW Winter barley *Hordeum vulgare* winter	F	PYRNTE Net blotch of barley *Pyrenophora teres*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
9	FR	HORVW Winter barley *Hordeum vulgare winter*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

10	FR	SECCW Winter rye *Secale cereale winter*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
11	FR	SECCW Winter rye *Secale cereale winter*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 0.195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
12	FR	TTLWI Triticale winter *Triticale sp. winter*	F	RHYNSE Leaf blotch of cereals Rhynchosporium secalis	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
13	FR	TTLWI Triticale winter *Triticale sp. winter*	F	LEPTNO Glume blotch of wheat Parastagonospora nodorum	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

14	FR	TTLWI Triticale winter *Triticale sp. winter*	F	FUSASP Fusarium ear blight of cereals Fusarium sp	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
15	FR	TTLWI Triticale winter *Triticale sp. winter*	F	PUCCST Stripe rust Puccinia striiformis	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
16	FR	TTLWI Triticale winter *Triticale sp. winter*	F	SEPTTR Speckled leaf blotch of wheat Zymoseptoria tritici	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 195 b) 195	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
17	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

18	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
19	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	LEPTNO Glume blotch of wheat *Parastagonospora nodor*um	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
20	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	FUSASP Fusarium ear blight of cereals *Fusarium sp*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)
21	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

22	FR	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PYRNTR Yellow leaf blotch of wheat *Pyrenophora tritici-repentis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
23	FR	HORVS Spring barley *Hordeum vulgare spring*	F	PUCCCHD Dwarf leaf rust of barley *Puccinia hordei*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
24	FR	HORVS Spring barley *Hordeum vulgare spring*	F	PYRNTE Net blotch of barley *Pyrenophora teres*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
25	FR	HORVS Spring barley *Hordeum vulgare spring*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

26	FR	SECCW Spring rye *Secale cereale spring*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 2 b) 2	14	a) 0.65 b) 1.3	a) 195 b) 390	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
27	FR	SECCW Spring rye *Secale cereale spring*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) 2 b) 2	14	a) 0.65 b) 1.3	a) 195 b) 390	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
28	FR	TTLSO Triticale spring *Triticale sp. spring*	F	RHYNSE Leaf blotch of cereals Rhynchosporium secalis	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
29	FR	TTLSO Triticale spring *Triticale sp. spring*	F	LEPTNO Glume blotch of wheat Parastagonospora nodorum	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)

30	FR	TTLSO Triticale spring *Triticale sp. spring*	F	FUSASP Fusarium ear blight of cereals Fusarium sp	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
31	FR	TTLSO Triticale spring *Triticale sp. spring*	F	PUCCST Stripe rust Puccinia striiformis	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
32	FR	TTLSO Triticale spring *Triticale sp. spring*	F	SEPTTR Speckled leaf blotch of wheat Zymoseptoria tritici	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 25 – 61	a) **1** b) **1**	-	a) 0.65 b) **0.65**	a) 195 b) **195**	200 - 400	F – the latest time of application must be growth stage BBCH 61 at the latest.	**Not acceptable** (risk to aquatic organisms)
33	FR	BRSNW Winter Oilseed rape *Brassica napus winter*	F	SCLESC Root rot *Sclerotinia sclerotiorum*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)

34	FR	BRSNW Winter Oilseed rape *Brassica napus winter*	F	ALTEBA black spot of rape *Alternaria brassicae*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)
35	FR	BRSNW Winter Oilseed rape *Brassica napus winter*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 16 - 19 (autumn application)	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 19 at the latest.	**Not acceptable** (efficacy, risk to aquatic organisms)
36	FR	BRSNW Winter Oilseed rape *Brassica napus winter*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 16 - 59 (spring application)	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 59 at the latest.	**Not acceptable** (efficacy, risk to aquatic organisms)
37	FR	BRSNS Spring Oilseed rape *Brassica napus spring*	F	SCLESC Root rot *Sclerotinia sclerotiorum*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)

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38	FR	BRSNS Spring Oilseed rape *Brassica napus spring*	F	ALTEBA black spot of rape *Alternaria brassicae*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 69 at the latest.	**Not acceptable** (risk to aquatic organisms)
39	FR	BRSNS Spring Oilseed rape *Brassica napus spring*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 16 - 59	a) 2 b) 2	21	a) 0.6 b) 1.2	a) 180 b) 360	200 - 400	F – the latest time of application must be growth stage BBCH 59 at the latest.	**Not acceptable** (efficacy, risk to aquatic organisms)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

TARTAROS (PROTHIOCONAZOLE 300 EC) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a transparent dark brown and slightly viscous liquid, with a mild sweetish odour. It is not explosive and has no oxidising properties. The product has no flash point up to 100 °C. It has a self-ignition temperature of 232 °C. In aqueous solution (1 % dilution), it has a pH value of 5.1 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE/PA containers. The technical characteristics are acceptable for an EC formulation.

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

The efficacy level of TARTAROS (PROTHIOCONAZOLE 300 EC) is considered acceptable for all the requested uses, except those against LEPTMA. Given the lack of data or possible extrapolation for the use against LEPTMA, the evaluation of the efficacy of TARTAROS (PROTHIOCONAZOLE 300 EC) on this pathogen cannot be finalised.

The phytotoxicity level of TARTAROS (PROTHIOCONAZOLE 300 EC) is considered negligible for all the requested uses. The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered negligible.

There is a risk of resistance developing or appearing to prothioconazole for *Zymoseptoria tritici, Fusarium* sp. and *Pyrenophora teres*. This requires monitoring and the setting-up of efficacy trials in situations of characterised resistance for *Z. tritici* and *P teres*. To avoid the development of resistance of *Z. tritici* and *P. teres* to prothioconazole, the number of applications is limited to one per crop cycle on wheat, triticale and barley.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurities (prothioconazole-desthio, prothioconazole-deschloro and toluene) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination

of residues of prothioconazole in plants (cereals and high-oil-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: **prothioconazole (PTZ)**			
ADI	0.01 mg/kg bw/d		EU (2008)
ARfD	0.01 mg/kg bw		
AOEL	0.2 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 300 g/L	Spray dilution (used in formulation) 0.45 g/L
	Dermal absorption endpoints %	**25**	**75**
Oral absorption %	**90**		

Substance: **desthio-prothioconazole (dPTZ)**			
ADI	0.01 mg/kg bw/d		Peer review Efsa (2007)
ARfD	0.01 mg/kg bw		
AOEL	0.01 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on the formulation TARTAROS:		
		Spray dilution tested (1) 0.113 g/L	Spray dilution tested (2) 0.225 g/L
		21.9	**16.3**
		Concentrate (used in formulation) Not applicable*	Spray dilution (used in formulation) 0.4 g/L
	Dermal absorption endpoints %	**0***	**16**
Oral absorption %	**90**		

(1) and (2) Tested Spray Dilutions corresponding respectively to 50 % and 100 % metabolism conversion rate of 0.3 L product (300 g/L) Q.S 400 L water/ha, without considering the molar mass (MM) differences between metabolite (dPTZ: 312.2 g/mol) and parent (PTZ: 344.3 g/mol). If MM differences had been considered with appropriate molar ratio of 0.907 (312.2/344.3) the exact dPTZ test concentrations should

have been 0.204 g/L (instead of 0.225 g/L) and 0.102 g/L (instead of 0.113 g/L) respectively for 100 % and 50 % conversion into dPTZ. However, this does not affect the overall outcome of the assessment.

** For the exposure assessment to prothioconazole-desthio, a 100 % conversion of prothioconazole to prothioconazole-desthio was assumed. Formation of prothioconazole-desthio is not expected in the concentrate, thus during the M/L task, dermal absorption of prothioconazole-desthio was not considered and a dermal absorption value of 0 % was applied to remove this from calculation.*

3.4.1 Acute toxicity

TARTAROS (PROTHIOCONAZOLE 300 EC), containing 300 g/L prothioconazole, has a low acute oral, inhalational and dermal toxicity, and is not a skin sensitiser, but is irritating to the skin and causes serious eye damage.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[9]	Equipment *Application method*	Maximum application rate (L PPP/ha and nº of applications) [g a.s./ha]	Minimum volume water (L/ha)
Cereals (1 app.)	F	Vehicle-mounted *Downward spraying*	**0.65 L/ha (1 app.)** 195 g PTZ/ha 177 g dPTZ/ha*	200
Cereals (2 app.)	F	Vehicle-mounted *Downward spraying with drift-reducing nozzles*	**0.65 L/ha (2 app.)** 195 g PTZ/ha 177 g dPTZ/ha*	200
Oilseed rape	F	Vehicle-mounted *Downward spraying*	**0.60 L/ha (2 app.)** 180 g PTZ/ha 163 g dPTZ/ha*	200

** Assuming 100 % conversion of PTZ to PTZ-desthio and taking into account the molar ratio of PTZ-desthio to PTZ (312.2/344.3 = 0.907)*

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[10]:

Crop	Equipment	PPE and/or working coverall	% AOEL PTZ	% AOEL dPTZ
Cereals (1 application)	Vehicle-mounted	Refer to → Cereals use - 2 applications (worst case)		

[9] Open field or glasshouse
[10] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Crop	Equipment	PPE and/or working coverall	% AOEL PTZ	% AOEL dPTZ
Cereals (2 applications)	Vehicle-mounted	No PPE	69	38
		Working coverall and gloves during mixing/loading	11	38
		Working coverall and gloves during mixing/loading and application	3.1	6.9
Oilseed rape	Vehicle-mounted	No PPE	65	35
		Working coverall and gloves during mixing/loading	10	35
		Working coverall and gloves during mixing/loading and application	2.9	6.5

According to the model calculations, it may be concluded that the risk for the operator using TARTAROS (PROTHIOCONAZOLE 300 EC) is acceptable with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop inspection/irrigation. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to be 18 % of the AOEL of prothioconazole and 68 % of the AOEL of prothioconazole-desthio (for cereal use - two applications (worst-case)).

It may be concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e., no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[11].

[11] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.*"

3.4.5 Resident exposure

- **Oilseed use:**

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and child).

Model (AOEM) - All pathways (mean) buffer zone of 3 metres – no drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**21**	**93**
Resident (adults)	**10**	**40**

- **Cereals use (1 application):**

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and child) considering a buffer zone of 3 metres.

Model (AOEM) - All pathways (mean) buffer zone of 3 metres – no drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**17**	**74**
Resident (adults)	**7.1**	**29**

- **Cereals use (2 applications):**

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology (**or** mitigation measures such as a buffer zone of 5 metres) are taken to reduce the resident exposure:

Model (AOEM) - All pathways (mean) buffer zone of 3 metres – drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**21**	**90**
Resident (adults)	**10**	**42**

3.4.6 Combined exposure

Not relevant (one active substance).

3.5 Residues and consumer exposure (Part B, Section 7)

Overall conclusion

For oilseed rape, wheat/triticale, rye and barley, the data available are considered sufficient for risk assessment. No exceedance of the current MRL of 0.15 mg/kg in oilseed rape, 0.2 mg/kg in barley, 0.1 mg/kg in wheat/triticale and 0.05 mg/kg in rye for prothioconazole as laid down in Reg. (EU) 396/2005 is expected. The chronic and short-term intakes of prothioconazole residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses on oilseed rape, wheat/triticale, rye and barley.

According to the available data, no specific mitigation measures should apply.

Moreover, considering triazole derivative metabolites (TDMs, triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), France as zRMS proposed a dietary risk assessment similar to the ones proposed by EFSA in the *Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted* (EFSA Journal 2018; 16(7):5376). Data gaps have been identified by EFSA. Nevertheless, France as zRMS is of the opinion that the chronic and short-term intakes of TDMs residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

Data required in post-authorization for prothioconazole

- 4 southern additional residue trials on barley and wheat and 4 northern additional residue trials on wheat, supporting intended GAP with analysis of 1,2,4-T, TA and TAA have to be provided in post registration
- 4 northern and 8 southern additional residue trials on barley, 8 northern and 8 southern additional residue trials on wheat supporting intended GAP with analysis of TLA have to be provided in post registration

Data gaps

Relevant for the risk assessment for TDMs identified at EU level:

- Storage stability data on 1,2,4-T, TA and TAA in high-acid-content commodities, on 1,2,4-T in high-protein-content commodities and on TLA in cereal straw, and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops.
- Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies, to determine the magnitude of TLA residues in products of animal origin.
- Rotational crops field residue trials supported by acceptable storage stability data on TDMs.

Summary for TARTAROS (PROTHIOCONAZOLE 300 EC)

Information on TARTAROS (PROTHIOCONAZOLE 300 EC) (KCA 6.8)

Crop	PHI for TARTAROS (PROTHIOCONAZOLE 300 EC)requested by applicant	PHI/withholding period* sufficiently supported for prothioconazole	PHI for TARTAROS (PROTHIOCONAZOLE 300 EC)proposed by zRMS	zRMS Comments (if different PHI proposed)
Wheat	BBCH 25-69	Yes	F**	-
Barley	BBCH 25-61	Yes	F**	-

Crop	PHI for TARTAROS (PROTHIOCONAZOLE 300 EC)requested by applicant	PHI/withholding period* sufficiently supported for prothioconazole	PHI for TARTAROS (PROTHIOCONAZOLE 300 EC)proposed by zRMS	zRMS Comments (if different PHI proposed)
Rye	BBCH 25-61	Yes	F**	-
Triticale	BBCH 25-69	Yes	F**	-
Oilseed rape	BBCH 16-59/61-69	Yes	F**	

* Purpose of withholding period to be specified.
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for TARTAROS
Crop group	Led by prothioconazole	
All crops	NR	NR

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of prothioconazole and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

The PECsw and PECsed calculations for the metabolite prothioconazole-desthio have not been considered acceptable since the formation fractions are under-estimated (please refer to Registration Report Part B, section 8 for more details).

PECgw values for prothioconazole and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance

and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses.

PECsw and PECsed calculations for the metabolite prothioconazole-desthio are not considered acceptable, therefore the risk assessment on aquatic organisms cannot be finalised for TARTAROS (PROTHIOCONAZOLE 300 EC) (please refer to Registration Report Part B, section 8 for more details).

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance prothioconazole is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***TARTAROS***

de la société	*HELM AG*
enregistrée sous le	*n°2018-1270*

Vu les conclusions de l'évaluation de l'Anses du 19 janvier 2021,

Considérant qu'un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

TARTAROS
AMM n°-

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Informations générales sur le produit	
Nom du produit	TARTAROS
Type de produit	Produit de référence
Titulaire	HELM AG Nordkanalstrasse 28 20097 HAMBURG Allemagne
Formulation	Concentré émulsionnable (EC)
Contenant	300 g/L - prothioconazole
Numéro d'intrant	323-2018.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 08 AVR. 2021

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15103202 Blé*Trt Part.Aer.* Fusarioses	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
00108034 Blé*Trt Part.Aer.* Helminthosporiose	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103214 Blé*Trt Part.Aer.* Rouille(s)	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103221 Blé*Trt Part.Aer.* Septoriose(s)	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15203201 Crucifères oléagineuses* Trt Part.Aer.*Maladies fongiques des siliques	600 mL/ha	2/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15203203 Crucifères oléagineuses* Trt Part.Aer.*Phoma	600 mL/ha	2/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni de déterminer l'efficacité du produit.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15203202 Crucifères oléagineuses* Trt Part.Aer.*Sclérotiniose	600 mL/ha	2/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103226 Orge*Trt Part.Aer.* Helminthosporiose et ramulariose	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103229 Orge*Trt Part.Aer.* Rhynchosporiose	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103205 Orge*Trt Part.Aer.*Rouille(s)	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103232 Seigle*Trt Part.Aer.*Rhynchosporiose	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103208 Seigle*Trt Part.Aer.*Rouille(s)	650 mL/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		

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Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

TARTAROS

Fongicide contre les maladies des céréales et colza.

TARTAROS est un fongicide de la famille chimique des triazolinthiones (proches des triazoles) qui se caractérise par sa haute performance d'efficacité et sa polyvalence sur de nombreuses maladies des céréales, permettant de lutter contre les maladies des tiges, des feuilles et du blé d'hiver, du blé durum, du seigle d'hiver et de printemps, de l'orge d'hiver et de printemps, du triticale d'hiver et de printemps et contre les maladies du colza d'hiver et de printemps.

Contient 300 g/L de prothioconazole (98% p/p) sous la forme d´émulsion concentrée

Numéro d´AMM: xxxxx

Danger

H302 – Nocif en cas d´ingestion.
H315 - Provoque une irritation cutanée.
H318 - Provoque des lésions oculaires graves.
H411 - Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
P273 - Éviter le rejet dans l'environnement.
P280 - Porter des vêtements de protection/ un équipement de protection / des yeux.
P305+P351+P338 - EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P310 - Appeler immédiatement un CENTRE ANTIPOISON ou un médecin.
P391 - Recueillir le produit répandu.
P501 - Éliminer le contenu/récipient dans une installation conformément à la réglementation nationale.
EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
SPe3: Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

PROTEGER DU GEL

BIEN AGITER AVANT USAGE

Company Logo and company details

Contenu: 1-5-10 litres

Batch No: se référer à la bouteille

CONDITIONS D'EMPLOI DU PRODUIT

IMPORTANT: Cette information est approuvée comme faisant partie de l'étiquette du produit. Toutes les instructions de cette section doivent être lues attentivement afin d'obtenir une utilisation sûre et réussie de ce produit.

MALADIES CONTROLEES

Blé

Rouille jaune (*Puccinia striiformis*), Septoriose du blé (*Zymoseptoria tritici*), Septoriose des épis (*Parastagonospora nodorum*), Brown rust (*Puccinia recondita*), Rouille brune (*Pyrenophora tritici-repentis*), *Fusarium sp.*

Orge

Rouille naine de l'orge (*Puccinia hordei*), taches brunes de l'orge (*Pyrenophora teres*), rhynchosporiose de l´orge (*Rhynchosporium secalis*)

Seigle

Rhynchosporiose du seigle (*Rhynchosporium secalis*), rouille brune (*Puccinia recondita*)

Triticale

Rhynchosporiose (*Rhynchosporium secalis*), Septoriose des épis (*Parastagonospora nodorum*), rouille jaune (*Puccinia striiformis*), Septoriose (*Zymoseptoria tritici*), *Fusarium sp.*

Colza de printemps et d hiver

Pourriture racinaire (*Sclerotinia sp.*), Maladie des taches noires (*Alternaria sp.*), Phoma leaf spot (*Plenodomus lingam*)

RECOMMANDATIONS D'USAGE

Céréales d´hiver : Appliquer à raison de 0,65 L de produit / ha dans 200-400 L d'eau / ha La dose totale maximale est de 0,65L/Ha/an (1 application).

Céréales de printemps : Appliquer à raison de 0,65 L de produit / ha dans 200 à 400 L d'eau / ha La dose totale maximale est de 1,3 L / ha/an (2 applications).

Septoriose (Zymoseptoria tritici) et Septoriose des épis *(Parastagonospora nodorum), bon contrôle :*
Appliquer avant que la maladie ne s'établisse dans la culture. Pour protéger les feuilles supérieures et l'épi, appliquer le produit du BBCH 25 (5 talles détectables) jusqu'au début de la floraison (BBCH 61). Lorsque la pression de la maladie reste élevée, l'application peut être répétée.

Rouille jaune (Puccinia striiformis), contrôle modéré :
Appliquer le produit dès les premiers signes de la maladie (BBCH 25-61). Une deuxième application peut être faite 2-3 semaines plus tard si une nouvelle infection se produit. Les applications faites aux infections établies sont susceptibles d'être moins efficaces.

Rouille brune (Puccinia recondita) et rouille naine (Puccinia hordei), bon contrôle:
Appliquer le produit dès les premiers signes de la maladie (BBCH 25-61). Une deuxième application peut être faite 2-3 semaines plus tard si une nouvelle infection se produit. Les applications faites aux infections établies sont susceptibles d'être moins efficaces.

Rouille brune du blé (Pyrenophora tritici-repentis), contrôle modéré:
Appliquer le produit dès les premiers signes de la maladie au printemps/été (BBCH 25-61). Lorsque la pression de la maladie reste élevée, l'application peut être répétée.

Fusarium sp., contrôle modéré:

Appliquer TARTAROS peu après la levée de l'épi jusqu'à la fin de la floraison (BBCH 61-69) pour un contrôle modéré de *Fusarium sp*. Le contrôle des maladies de l'épi peut donner des épi plus propres et plus brillants. Grâce à la réduction du mildiou, TARTAROS réduit efficacement le taux de mycotoxine désoxynivalénol (DON) dans les grains de blé. Cependant, lorsque les niveaux de Fusarium sont élevés, la réduction obtenue peut ne pas toujours être suffisante pour s'assurer que les niveaux de DON tombent en dessous de la limite légale.

Taches brunes *(Pyrenophora teres),* bon contrôle:
Appliquer le produit dès les premiers signes de la maladie au printemps/été (BBCH 25-61). Une deuxième application peut être faite 2-3 semaines plus tard si une nouvelle infection se produit. Les applications faites aux infections établies sont susceptibles d'être moins efficaces.

Rhynchosporiose *(Rhynchosporium secalis), bon contrôle :*

Appliquer le produit dès les premiers signes de la maladie au printemps (BBCH 25-61). Une deuxième application peut être faite 2-3 semaines plus tard si une nouvelle infection se produit.

Colza d´hiver : Appliquer 0,6 L de produit / ha dans 200 à 400 L d'eau / ha. La dose totale maximale par culture est de 1,2 L / ha/an (2 applications).

Les volumes de pulvérisation les plus élevés sont recommandés lorsque la culture est dense ou que la pression de la maladie ou le risque est élevé afin d'assurer une bonne pénétration des feuilles inférieures et des bases de la tige. Le contrôle des maladies peut être compromis en réduisant les volumes d'eau, où une bonne couverture de pulvérisation est difficile à atteindre.

Phoma (Plenodomus lingam) : Appliquer TARTAROS en automne ou printemps dès les premiers signes de la maladie (BBCH 61-69). Répéter l´application au printemps si les symptômes réapparaissent après la première application en automne.

Pourriture racinaire (*Sclerotinia sp.*), Maladie des taches noires (*Alternaria sp.*) : Appliquer TARTAROS du début à la pleine floraison (BBCH 61-69).

Colza de printemps: Appliquer 0,6 L de produit / ha dans 200 à 400 L d'eau / ha. La dose totale maximale par culture est de 1,2 L / ha/an (2 applications).

Les volumes de pulvérisation les plus élevés sont recommandés lorsque la culture est dense ou que la pression de la maladie ou le risque est élevé afin d'assurer une bonne pénétration des feuilles inférieures et des bases de la tige. Le contrôle des maladies peut être compromis en réduisant les volumes d'eau, où une bonne couverture de pulvérisation est difficile à atteindre.

Phoma (Plenodomus lingam), bon contrôle : Appliquer TARTAROS au printemps dès les premiers signes de maladie (BBCH 16-59).

Pourriture racinaire *(Sclerotinia sp.),* réduction : Appliquer TARTAROS du début à la pleine floraison (BBCH 61-69).

Maladie des taches noires *(Alternaria sp.),* contrôle modéré : Appliquer TARTAROS du début à la pleine floraison (BBCH 61-69).

MELANGE ET APPLICATION

Bien agiter avant utilisation. Ajouter la quantité requise de TARTAROS dans le réservoir de pulvérisation à moitié rempli avec le système d'agitation en marche, puis remplir au niveau requis. Poursuivre l'agitation pendant la pulvérisation et jusqu'à ce que le réservoir soit complètement vide. Pulvériser immédiatement après mélange. Une pression de pulvérisation de 2-3 bars est recommandée. Les pulvérisateurs doivent être soigneusement nettoyés avant utilisation, et les filtres et les jets doivent être vérifiés pour déceler les dommages et les blocages. La hauteur de la rampe doit être ajustée pour assurer une couverture uniforme de la culture, en particulier aux stades de croissance ultérieurs. La hauteur correcte est celle à laquelle la pulvérisation des buses alternées se rencontre juste au-dessus de la culture. Dans les cultures denses, à des stades de croissance ultérieurs, des volumes d'eau plus élevés devraient être utilisés. Bien laver tous les pulvérisateurs et appareils de mesure avec de l'eau immédiatement après usage.

SECURITE DES CULTURES

D'après notre expérience, l´utilisation de TARTAROS est sûre dans toutes les variétés de blé, d'orge, de seigle, de triticale et de colza lorsqu'il est utilisé aux doses d'application recommandées.

RESISTANCE

L'application répétée de TARTAROS seul ne doit pas être utilisée sur la même culture contre un agent pathogène à risque élevé. Des mélanges ou une alternance avec des fongicides ayant un mode d'action différent (par exemple des morpholines) se sont révélés protéger contre le développement de formes résistantes de la maladie. Le développement possible de souches de maladies résistantes à TARTAROS ne peut être exclu ou prédit. Lorsque de telles souches résistantes apparaissent, il est peu probable que TARTAROS donne un contrôle satisfaisant. Pour éviter le développement d'une résistance, appliquer le produit de manière protectrice en réponse aux prévisions de la maladie.

TANK-MIXING

The mixtures must be used in accordance with the regulations in force and the recommendations of the guides of good agricultural practices.Tank mixes should be applied immediately after mixing and mixes with more than 3 partners are generally not recommended.

Les mélanges doivent être utilisés conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques agricoles. Les mélanges doivent être appliqués immédiatement après préparation de la bouillie et les mélanges avec plus de 3 produits ne sont généralement pas recommandés.

APPLICATION

Méthode d'application : Pulvérisateur porté / traîné. Une pression de pulvérisation de 2-3 bars est recommandée. Appliquer en qualité de pulvérisation moyenne. Appliquer TARTAROS dans 200 à 400 litres d'eau par hectare. Les volumes de pulvérisation les plus élevés sont recommandés lorsque la culture est dense ou que la pression de la maladie ou le risque est élevé afin d'assurer une bonne pénétration dans les feuilles inférieures et les bases des tiges. Le contrôle des maladies peut être compromis en réduisant les volumes d'eau, dans les situations où une bonne couverture de pulvérisation est difficile à atteindre.

La hauteur de la rampe doit être ajustée pour assurer une couverture uniforme de la culture, en particulier aux stades de croissance ultérieurs. La hauteur correcte est celle où la pulvérisation des buses de remplacement se trouve juste au-dessus de la culture, dans les cultures denses, à des stades de croissance ultérieurs, des volumes d'eau plus élevés devraient être utilisés.

PREPARATION DE LA BOUILLIE

Bien agiter le produit avant utilisation. Ajouter la quantité requise de TARTAROS dans le réservoir de pulvérisation à moitié rempli avec le système d'agitation en fonctionnement, puis remplir jusqu'au niveau requis. Poursuivre l'agitation pendant la pulvérisation et jusqu'à ce que le réservoir soit complètement vide. Pulvériser immédiatement après le mélange.

NETTOYAGE DE L'EQUIPEMENT D'APPLICATION

L'équipement de pulvérisation doit être soigneusement nettoyé à l'eau après utilisation.

EQUIPEMENT DE PROTECTION INDIVIDUEL

Pour l'opérateur, dans le cadre d'une application effectuée à l'aide d'un pulvérisateur a rampe, porter

- *Pendant le mélange / chargement*
  - Gants en nitrile certifies EN 374-3 ;
  - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
  - EPI partiel (blouse ou tablier a manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
  - Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3),
- *Pendant application*

  Si application avec tracteur avec cabine

  Combinaison de travail en polyester 65 % /coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;

  Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation a l'extérieur de la cabine,

  Si application avec tracteur sans cabine

  Combinaison de travail en polyester 65 % /coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;

  Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- *Pendant le nettoyage du matériel de pulvérisation*

- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail en polyester 65 % /coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

Pour le travailleur amené à entrer dans la culture après traitement, porter une combinaison de travail (cotte en coton/polyester 35%/65% - grammage d'au moins 230 g/m²) avec traitement déperlant.